

Docket No.: 290624US0PCT

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF: : EXAMINER: MORRIS, P.  
Hiroshi NAGASAWA, ET AL : GROUP ART UNIT: 1625  
SERIAL NO.: 10/578,844 : U.S. PATENT NO.: 7,547,786  
FILED: MAY 10, 2006 : ISSUED: JUNE 16, 2009

FOR: PROCESS FOR PRODUCING THIAZOLE DERIVATIVE

PETITION UNDER 37 C.F.R. §1.705(d) AND  
REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT

COMMISSIONER FOR PATENTS  
P.O. BOX 1450  
ALEXANDRIA, VA 22313-1450

SIR:

Petitioners hereby request reconsideration of the final patent term adjustment for U.S. Patent No. 7,547,786 (“the ‘786 patent”) of 282 days and, in place thereof, Petitioners request that the patent term adjustment be changed to 153 days.

Petitioners contend that the Office erred in determining patent term adjustment published on the face of the ‘786 patent by not properly accounting for the period of time where issuance of the ‘786 patent was delayed beyond three years of pendency (35 U.S.C. §154(b)(1)(B)).

Correction of the foregoing error in the patent term adjustment is requested in view of the present Petition including the facts and remarks that follow.

Patent Term Adjustment indicated in the Notice of Allowance and on the '786 Patent:

On February 10, 2009, a Notice of Allowance was issued in U.S. Application Serial No. 10/578,844, which indicated that the determination of patent term adjustment under 35 U.S.C. §154(b) was 116 days. This patent term adjustment represents the 239-day period in which the Office failed to mail of either an action under 35 U.S.C. §132, or a notice of allowance under 35 U.S.C. §151 following expiration of 14 months from filing (37 C.F.R. §1.703(a)(1)) from which a total of 123 days have been subtracted in which Petitioner failed to engage in reasonable efforts to conclude prosecution (processing or examination) of the application (37 C.F.R. §1.704(a)).

On June 16, 2009, the Office issued U.S. 7,547,786. On the face of the '786 patent a patent term adjustment of 116 days is indicated. Petitioners submit that the Office improperly determined the number of additional days that should have been added for delays beyond three years of pendency (35 U.S.C. §154(b)(1)(B)). Accordingly, for the reasons that follow, Petitioners should be entitled to an additional 37 days of patent term adjustment for delays beyond three years of pendency (35 U.S.C. §154(b)(1)(B)).

Statute relevant to decision on Petition:

35 U.S.C. §154(b) provides for the patent term guarantees giving rise to an adjustment in patent term.

Specifically, 35 U.S.C. §154(b)(1) provides for the following adjustments to the patent term:

(1) PATENT TERM GUARANTEES.-

(A) GUARANTEE OF PROMPT PATENT AND TRADEMARK OFFICE RESPONSES.- Subject to the limitations under paragraph (2), if the

issue of an original patent is delayed due to the failure of the Patent and Trademark Office to-

- (i) provide at least one of the notifications under section 132 of this title or a notice of allowance under section 151 of this title not later than 14 months after-
  - the date on which an application was filed under section 111(a) of this title; or
  - the date on which an international application fulfilled the requirements of section 371 of this title;
- (ii) respond to a reply under section 132, or to an appeal taken under section 134, within 4 months after the date on which the reply was filed or the appeal was taken;
- (iii) act on an application within 4 months after the date of a decision by the Board of Patent Appeals and Interferences under section 134 or 135 or a decision by a Federal court under section 141, 145, or 146 in a case in which allowable claims remain in the application; or
- (iv) issue a patent within 4 months after the date on which the issue fee was paid under section 151 and all outstanding requirements were satisfied, the term of the patent shall be extended 1 day for each day after the end of the period specified in clause (i), (ii), (iii), or (iv), as the case may be, until the action described in such clause is taken.

**(B) GUARANTEE OF NO MORE THAN 3-YEAR APPLICATION**

**PENDENCY.**- Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States, not including-

- (i) any time consumed by continued examination of the application requested by the applicant under section 132(b);
- (ii) any time consumed by a proceeding under section 135(a), any time consumed by the imposition of an order under section 181, or any time consumed by appellate review by the Board of Patent Appeals and Interferences or by a Federal court; or
- (iii) any delay in the processing of the application by the United States Patent and Trademark Office requested by the applicant except as permitted by paragraph (3)(C), the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued.

(C) GUARANTEE OR ADJUSTMENTS FOR DELAYS DUE TO INTERFERENCES, SECRECY ORDERS, AND APPEALS.- Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to-

- (i) a proceeding under section 135(a);
- (ii) the imposition of an order under section 181; or
- (iii) appellate review by the Board of Patent Appeals and Interferences or by a Federal court in a case in which the patent was issued under a decision in the review reversing an adverse determination of patentability, the term of the patent shall be extended 1 day for each day of the pendency of the proceeding, order, or review, as the case may be.

Countering this period is the limitations enunciated in 35 U.S.C. §154(b)(2), which sets forth:

(2) LIMITATIONS.-

- (A) IN GENERAL.- To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.
- (B) DISCLAIMED TERM.- No patent the term of which has been disclaimed beyond a specified date may be adjusted under this section beyond the expiration date specified in the disclaimer.

(C) REDUCTION OF PERIOD OF ADJUSTMENT.-

- (i) The period of adjustment of the term of a patent under paragraph (1) shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application.
- (ii) With respect to adjustments to patent term made under the authority of paragraph (1)(B), an applicant shall be deemed to have failed to engage in reasonable efforts to conclude processing or examination of an application for the cumulative total of any periods of time in excess of 3 months that are taken to respond to a notice from the Office making any rejection, objection, argument, or other request, measuring such 3-month period from the date the notice was given or mailed to the applicant.
- (iii) The Director shall prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage

in reasonable efforts to conclude processing or examination of an application.

Grounds for Request for Reconsideration and Reinstatement of Patent Term Adjustment:

At issue in this case is the Office's misapplication of the provision in 35 U.S.C. §154(b)(2) that states "To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed."

On the face of the '786 patent a patent term adjustment of 116 days is indicated. The Office determination of the 116-day patent term adjustment is in error in that, pursuant to 35 U.S.C. § 154(b)(l)(B), the Office failed to properly allow an adjustment for the time exceeding three years after the actual filing date of the present application (May 10, 2006) to the date when the '786 patent issued (June 16, 2009). The correct patent term adjustment for the '786 patent is 153 days.

In this case, the period of patent term adjustment under 35 U.S.C. §154(b)(1)(A) and 35 U.S.C. §154(b)(1)(B) are calculated independently. The following is a summary of the time periods and the number of days of PTA:

*35 U.S.C. §154(b)(1)(A)*

**Plus 239 days** from July 10, 2007 (i.e., 14 months from the filing date (i.e., May 10, 2006) to March 5, 2008, when Office mailed a Restriction Requirement (i.e., an action under 35 U.S.C. §132) (35 U.S.C. §154(b)(1)(A)(i) and 37 C.F.R. §1.703(a)(1)).

TOTAL patent term adjustment under 35 U.S.C. §154(b)(1)(A) = **239 days**.

*35 U.S.C. §154(b)(1)(B)*

**Plus 37 days** from May 10, 2009 (i.e., 3 years from the filing date of May 10, 2006) to June 16, 2009 when the patent issued (35 U.S.C. §154(b)(1)(B)).

TOTAL patent term adjustment under 35 U.S.C. §154(b)(1)(B) = **37 days**.

*35 U.S.C. §154(b)(2)(C) correction*

**Minus 123 days** due to Petitioners' failure to engage in reasonable efforts to conclude prosecution of the application (35 U.S.C. §154(b)(2)(C) and 37 C.F.R. §1.704(a)) for the periods of (a) April 3, 2008 to June 4, 2008 (62 days) and (b) September 18, 2008 to November 18, 2008 (61 days).

TOTAL correction to patent term adjustment under 35 U.S.C. §154(b)(2)(C) = **123 days**.

35 U.S.C. §154(b)(2) states "To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed."

In *Wyeth v. Dudas*, Civil Action No. 07-1492 (JR) (2008 U.S. Dist. Lexis 76063 (D.D.C., September 30, 2008), copy **enclosed herewith**, the Court issued an opinion explaining the proper method for calculating patent term adjustments under 35 U.S.C. § 154(b). Specifically, when determining the overlap defined in 35 U.S.C. §154(b)(2), the *Wyeth* Court held that "[t]he only way that [A and B] periods of time can 'overlap' is if they occur on the same day" (see page 3, left column, first fully paragraph). In other words, the A delay (i.e., delay under 35 U.S.C. §154(b)(1)(A)) and B delay (i.e., delay under 35 U.S.C. §154(b)(1)(B)) only overlap if the A delay occurs after three years of pendency.

With this proper frame of reference, Petitioners return to the calculation above. In this case, there is no overlap between the A delay and the B delay.

The resulting calculation of the patent term adjustment for the '786 patent should be as follows:

A delay	B delay	35 U.S.C. §154(b)(2) correction	Applicant Delay	Total PTA
239	+ 37	- 0	- 123	= 153

In view of the foregoing and supported by *Wyeth v. Dudas*, Petitioners respectfully request that the Office correct the errors in the patent term adjustment for the '786 patent and properly indicate that the patent term adjustment has been changed to 153 days.

In accordance with the provisions of 37 C.F.R. §1.704(b) and (d), Petitioners submit herewith the requisite fee under 37 C.F.R. §1.18(e). In the event that the Office determines that additional fees are required, it is requested that any underpayment be charged to their undersigned Representative's deposit account (Deposit Account No. 15-0030).

For the foregoing reasons, Petitioners respectfully submit that the Request for Reconsideration of the Patent Term Adjustment of U.S. 7,547,786 should be GRANTED and the patent term adjustment should properly be indicated as 153 days. Early notification of such action is earnestly solicited.

Respectfully submitted,  
OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, L.L.P.

Customer Number

22850

Tel: (703) 413-3000  
Fax: (703) 413-2220



Vincent K. Shier, Ph.D.  
Registration No. 50,552